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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,148	09/12/2003	Richard W. Duerst	7090US01	6797

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EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,148

Applicant(s)

DUERST ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/30/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-26, 28-47, 52 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6350869, US 6093814, 4935507, WO 03050124, WO 9955710 A, JP 02000790 A2, WO 1079211 A1, WO2046175 A1, Inamoto, González,. EP 1273587, WO 03050124 or US 4559334.

Claims 1-26, 28-47, 52 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 2003091261.

In WO 9955710 does not have an actual crystallization of cefdinir, but claim 9 names cefdinir, which puts this product into the public domain. In WO 2098884 A1, see examples 3 and 4. In González, see example 3.11.

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In US 6350869, see example 3. In US 6093814 A, see examples 6-8. In JP 02000790 A2, see working example 2 on pages 27-28 of the translation. In WO 1079211 A1, see the operational examples 1-19 on pages 11-14 of the translations, all of which make cefdinir. In WO2046175 A1, see Reference Example 1-(3) on page 7 of the translation. In Inamoto, see sentence bridging columns 1-2 of page 828, and note that FK 482 is cefdinir. In WO 03050124, see example 4 (a copy of reference is provided; the document sent to the PTO was WO 03/005124, the wrong document. It is the equivalent of US 20050080255 A1). In EP 1273587 (this is the English language version; original publication date as noted was 10/25/2001), see the working examples. In 4559334, see example 14. In WO 2003091261, see example 4. In the references in this paragraph, the crystallization is from water, one of the named solvents, so that the technique is fairly similar, though not the same, as that recited in claim 3.

In 4935507, data is given, but it is unclear whether this is a different form because the method of characterization is somewhat different. The process uses crystallization from water, from alcohol or from an aqueous alcohol, and thus resembles claims 3-4 and 20.

These forms differ from the claim in that the reference is silent on the crystalline form. But applicants must show that their crystalline form really is different from any of the ones prepared in the prior art. MPEP 2112 states:

"SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

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In this case, the “unknown property” is the particular crystalline form. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state:

“A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection.”

Again, the “CHARACTERISTIC” which the prior art is silent on is the crystalline form.

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also Ex parte Anderson, 21 USPQ 2nd 1241 at 1251, discussion of Rejection E. There, the decision states, “There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture.” (page 1253). The “properties” branch of that statement applies here.

Applicants are reminded that the PTO has no testing facilities.

In claim 52, the claim is anticipated even in the crystalline form is different. A carrier would include an aqueous solution. Such a solution would dissolve the crystalline

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form, and as a result, the same solution would be obtained regardless of which form was started with.

Claims 1-47, 49, 52 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 2098884 A1.

See example 4. The cefdinir being "dispersed" in aqueous ethanol would be understood as forming a suspension, because otherwise it would say dissolved. This appears to be applicants' actual process. The reference is the published equivalent of US 20040210049 A1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48, 50 and 51 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2098884 A1.

This are just routine variations. Varying a temperature (here, 23° vs. 30°) is just a routine variation, as is running a reaction longer to get the best yield. With regard to claim 48, it is obvious to do a reaction at any plausible scale.

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The examiner notes US 20030204082, US 20040242556, and WO 2004085443 (and WO 2004104010, which may well be the same form) and the fact that the data therein appears to show that these are different forms than what is present here.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-48 are garbled, as these should have "made by the process of Claim 27".

Note that claim 27 is a process claim.

Claim Objections

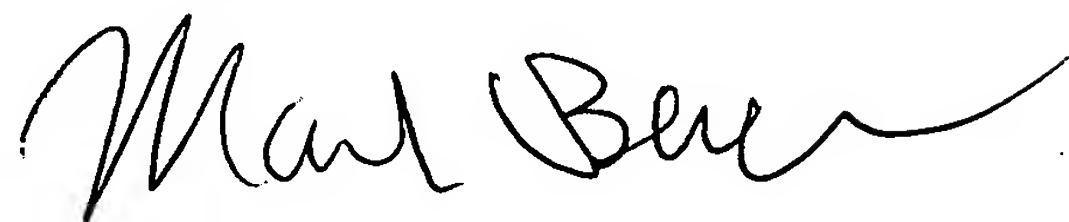
Claims 2-26 and 28-47 are objected to as unduly multiplied. Applicants have exactly one crystalline form of one compound. Thus, these 45 claims are all drawn to the same thing, as the specification teaches that each process produces the same thing. Thus, the claims are unduly multiplied.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Berch
Primary Examiner
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8/30/05